PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
FRANK J. UXA
STOUT, UXA, BUYAN & MULLINS, LLP
4 VENTURE
SUITE 300
IRVINE, CA 92618

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

	Date of mailing *(day/month/year)* [illegible]
Applicant's or agent's file reference D-3186PCT	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US05/02710	28 January 2005 (28.01.2005)	30 January 2004 (30.01.2004)

International Patent Classification (IPC) or both national classification and IPC

IPC(7): B65D 47/18 and US Cl.: 222/420,214,215,567,; 604/295

Applicant

MANESIS, NICK

1. This opinion contains indications relating to the following items:

☒	Box No. I	Basis of the opinion
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(*b*) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer Mar Y Michael Telephone No. 703-305-0861

Form PCT/ISA/237 (cover sheet) (January 2004)

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US05/02710

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ in written format

☐ in computer readable form

c. time of filing/furnishing

☐ contained in international application as filed.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US05/02710

Box No. V Reasoned statement under Rule 43 *bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 1-21	YES
	Claims NONE	NO
Inventive step (IS)	Claims NONE	YES
	Claims 1-21	NO
Industrial applicability (IA)	Claims 1-21	YES
	Claims NONE	NO

2. Citations and explanations:

Claims 1-21 meet the criteria set forth in PCT Article 33(4) because the claimed subject matter can be made and/or used in industry.

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

Supplemental Box
In case the space in any of the preceding boxes is not sufficient.

V. 2. Citations and Explanations:
Claims 1, 2, 4-11,17, 18, 20 and 21 lacks inventive step under PCT Article 33 (3) as being obvious over Hagele (US 6,129,248) in view of Brown (US 2,237,213).

Referring to claims 1, 6, 7, 18, and 20, Hagele discloses a body (fig 6) having a first end (40, fig 6), and opposing second end (26, fig 6), and an inner wall (22, fig 6) defining a conduit extending through the body (10, fig 6) to pass an ophthalmic composition from a container (4, fig 3), which is coupled to the second end (26, fig 6) of the body, to the first end (40, fig 6) of the body; and

an ophthalmic composition dispensing element (col 2, lines 63-65) located at the first end of the body, the dispensing element (50, fig 6) comprising a dispensing orifice (20, fig 6) of the conduit, the dispensing element (50, fig 6) being structured to dispense drops of the ophthalmic composition from the body (col 2, lines 63-65) but does not include the drops having a maximum relative deviation of size less than 10 percent according to the claim. Brown however discloses the drop dispenser devised the approximate deviation for the same quantity will be about 2%.

It would have been obvious to one of ordinary skill in the art to have used the construction of the dropper of Brown in the dropper tip of Hagele in order to continuously have a drop of the same size and quantity as taught by Brown.

Referring to claim 2, Hagele further discloses the conduit (22, fig 6) comprises a dispensing portion defined by a first inner wall portion (32, fig 6) extending from the dispensing orifice (20, fig 6), and a second conduit (24, fig 6) portion defined by a second inner wall (end of conduit) portion extending from the dispensing portion (fig 5) toward the second end of the body (26, fig 6), the dispensing portion (fig 5) having a maximum diameter (54, fig 5) that is greater than a maximum diameter of the second conduit portion (bottom end diameter of 24, fig 6).

Referring to claim 4, Hagele further discloses the dispensing portion (fig 5) has a length and the diameter of the dispensing portion decreases (fig 6, 22 and 32) from the dispensing orifice (20, fig 5) toward the second conduit portion (bottom end closer to 26, fig 6).

Referring to claim 5, Hagele further discloses the maximum diameter of the second conduit portion (end of conduit towards the end 26, fig 6) is less than a minimum diameter of the dispensing portion (orifice 20, fig 6).

Referring to claim 8, Hagele further disclose a dispensing element has an inner diameter (21, fig 5) and an outer diameter (of 40, fig 6) whose the ratio seems that it is in the range from about .5 to 1 to .93 to 1.

Referring to claim 9, Hagele further disclose a dispensing element has an inner diameter (21, fig 5) but does not disclose the ratio of the inner diameter to the outer diameter is greater than .75 to 1. It would have been obvious to one of ordinary skill in the art to have a dropper whose inner and outer range can be modified relative to the size of the drop desired.

Referring to claims and 10 and 11, Hagele further discloses a dispensing element (fig 6) comprises a sidewall (22, fig 6) forming the dispensing orifice (20, fig 6) of the conduit (24, fig 6), the dispensing orifice (20, fig 6) having a diameter, and the side wall which seems to have a thickness in a range from about 0.1% to about 20% or between about 9.0% to about 16% of the dispensing orifice diameter

Supplemental Box
In case the space in any of the preceding boxes is not sufficient.

(20). It would have been obvious to one of ordinary skill in the art to have created a wall thickness of any size in order to achieve the desired size of drop.

Referring to claim 17, Hagele further discloses a dropper tip (fig 6) attached to a container (4, fig 3, col 2, lines 63-65) containing an ophthalmic composition.

Referring to claim 21, forming a material into a body having a first end (30, fig 6), and opposing second end (26, fig 6), and inner wall (22, fig 6) defining a conduit (24) extending through the body (fig 6) to provide a flow path from the second end (26) to the first end (30), the first end (30) of the body including an ophthalmic composition dispensing element (fig 6) which comprises a dispensing orifice (20) of the conduit (24), the dispensing element (fig 6) being formed to dispense drops of the ophthalmic composition (col 2, lines 63-65) from the body, the drops having a maximum relative deviation of size less than 10 percent. but does not include the drops having a maximum relative deviation of size less than 10 percent according to the claim. Brown however discloses the drop dispenser devised the approximate deviation for the same quantity will be about 2%.

It would have been obvious to one of ordinary skill in the art to have used the construction of the dropper of Brown in the dropper tip of Hagele in order to continuously have a drop of the same size and quantity as taught by Brown.

Claim 3 lacks inventive step under PCT Article 33 (3) as being obvious over Hagele (US 6,129,248) in view of Brown (US 2,237,213) and further in view of Pirila (4,936,498).

Referring to claim 3, Hagele discloses a dispensing portion of the conduit has a length and the diameter of the dispensing portion but does not disclose the conduit is substantially constant along the length. Pirila however discloses a dispensing portion in which the conduit (6, fig 2) is constant along the length.

It would have been obvious to one of ordinary skill in the art to have modified the conduit of Hagele with a conduit of constant length of Pirila in order to make sure the flow of drop is not constricted at any point as taught by Pirila.

Claims 12-15 and 19 lacks inventive step under PCT Article 33 (3) as being obvious over Hagele (US 6,129,248) in view of Brown (US 2,237,213) and further in view of Gibilsco (5,221,027).

Referring to claims 12-15 and 19, Hagele discloses a dispensing dropper tip according to the claim but does not include a protection member surrounding the dispensing element to protect the dispensing element in the shape of a ring circumscribed around the dispensing member extending beyond the dispensing orifice forming a cavity having a bottom surface from which the dispensing element extends. Gibilsco discloses a protection member (2, fig 2) surrounding the dispensing element (1, fig 2) to protect the dispensing element in the shape of a ring (2, fig 2) circumscribed around the dispensing member (1, fig 2) extending beyond (fig 1) the dispensing orifice (end of 1, fig 1) forming a cavity (3) having a bottom surface (4) from which the dispensing element (1) extends.

It would have been obvious to one of ordinary skill in the art to have taken the dropper tip of Hagele and modified it by adding the protection member of Gibilsco in order to prevent the dispensing element from touching the eye as taught by Gibilsco.

Claim 16 lacks inventive step under PCT Article 33 (3) as being obvious over Hagele (US 6,129,248) in view of Brown (US 2,237,213) and further in view of Davis et al (5,040,706).

Referring to claim 16, Hagele discloses a dropper tip discloses the body has a first longitudinal axis (21,fig 6) but does not disclose the dispensing element has a second longitudinal axis being oriented at an angle from about zero degrees to about ninety degrees with respect to the first longitudinal axis according to the claim. Davis et al further discloses the dispensing element (fig 5) has a second longitudinal axis (angled towards opening 40, fig 3) being oriented at an angle from about zero degrees to ninety degrees (45 degrees, fig 5) with respect to the first longitudinal axis.

It would have been obvious to one of ordinary skill in the art to have added a second longitudinal axis of Davis et al to the dropper tip of Hagele in order to allow the person to look directly into a mirror to observe the location and orientation of the delivery device as taught by Davis et al.

NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under Article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the *PCT Applicant's Guide*, a publication of WIPO.

In these Notes, "Article," "Rule" and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions, respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only.

What parts of the international application may be amended ?

Under Article 19, only the claims may be amended

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Preliminary Examining Authority

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

When ? Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to file the amendments ?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

How ? Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Administrative Instructions, Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

What documents must/may accompany the amendments ?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.